

Ms Marianne Klingbeil Director, Secretariat General, Directorate C Acting Chair of the IAB, European Commission B - 1049 Bruxelles BELGIUM

1 1 JAN, 2011

Rue du Trône 108 Troonstraat B-1050 Brussels Belgium



Tel +32(0)2/627 88 80 Fax +32(0)2/627 88 81

Dear Madam,

In the context of the forthcoming revision of the Tobacco Products Directive, the Commissions' Directorate General for Health and Consumers Affairs has commissioned from RAND Europe a study entitled: "Assessing the Impacts of Revising the Tobacco Products Directive – Study to support a DG SANCO Impact Assessment", published in September 2010 ("the RAND report).

As this document is supposed to form the basis of the Commission's impact assessment in view of the possible revision of this Directive, the quality and impartiality of the study will be of the highest importance to a fair regulatory process.

The RAND report does not in our view meet the Commission's standards and we have expressed our concerns in the attached commentary which we thought would be of interest to you not only as the Director responsible for Better Regulation and Impact Assessment, but also in your capacity as Acting Chair of the Impact Assessment Board.

We have of course made our concerns known to the Director General of DG SANCO, Ms Testori Coggi, and enclose a copy of our letter of today.

Please also note that, at our request, Prof. Jonathan Klick has drafted a professional commentary of the RAND report and its technical and methodological flaws. Dr Klick sent his comments to Ms Testori Coggi, and we enclose a copy of this letter for your complete information.

As a draft Impact Assessment for the revision of the TPD will no doubt reach the Board in a not too distant future we thought it appropriate to draw your attention to the current shortcomings in this process.

Yours sincerely

Jack Bowles

Regional Director, Western Europe

Encl.



1 1 JAN 2011

Ms P. Testori Coggi, Director General DG SANCO European Commission B - 1049 Bruxelles BELGIUM Rue du Trône 108 Troonstraat B-1050 Brussels Belgium

Tel +32(0)2/627 88 80 Fax +32(0)2/627 88 81

Dear Director General,

We are grateful for the opportunity to comment on the study commissioned from RAND Europe by your services: "Assessing the Impacts of Revising the Tobacco Products Directive – Study to support a DG SANCO Impact Assessment", published in September 2010 ("the RAND report).

As this document is supposed to form the basis of the Commission's impact assessment in view of the possible revision of this Directive, the quality and the impartiality of the study will be of the highest importance to a fair regulatory process.

You will see from our attached commentary that the RAND report does not in our view meet the high standards expected from the Commission and that this raises serious concerns for the next steps in the proposed regulatory process.

We would of course be happy further to discuss these issues with yourself and members of your staff should you wish to do so.

Yours sincerely.

Jack Bowles

Regional Director, Western Europe

Encl.



## EUROPEAN COMMISSION SECRETARIAT-GENERAL

Deputy Secretary General

Brussels, SG.C2/HMC/ec Ares(2011)

Mr. Jack Bowles Regional Director, Western Europe British American Tobacco Brussels Rue du Trône 108 B-1050 Brussels Belgium

Dear Mr. Bowles,

Thank you for your letter of 11 January 2011 and the enclosed comments from both British American Tobacco and from Professor Klick on the RAND report ("Assessing the Impact of Revising the Tobacco Products Directive – Study to support a DG SANCO Impact Assessment"). I note you have also raised your concerns with Ms. Testori Coggi.

In your enclosure, you call for stakeholders to be given a further opportunity to comment on the draft impact assessment. However, as outlined in the recent Smart Regulation Communication, the Commission does not believe it is necessary to undertake specific consultations on draft impact assessments in addition to the range of other consultation mechanisms which are used by its Services.

Yours sincerely,

Marianne Klingbeil

h. Klingeric

CC:

P. Testori Coggi, M. Gremminger